The FDA Food Safety Modernization Act of 2009
Section-by-Section Summary

Title I – Improving Capacity to Prevent Food Safety Problems

Sec. 101. Inspection of Records – Gives FDA expanded access to food facility records if the Secretary has a reasonable belief that a related article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Also gives FDA access to records where there is a reasonable probability that a food, or a related article of food, will cause serious adverse health consequences or death to humans or animals.

Sec. 102. Registration of Food Facilities – Expands current registration requirements for food facilities by requiring all food facilities to register and renew registration biennially. Grants FDA authority to adjust food registration categories. Gives the Secretary authority to suspend facility registration if there is a reasonable probability that food from the facility will cause serious adverse health consequences or death to humans or animals.

Sec. 103. Hazard Analysis and Risk-Based Preventative Controls – Requires all registered domestic facilities to identify known or reasonably foreseeable hazards and implement preventive controls to significantly minimize or prevent those identified hazards. Each owner or operator is required to have a written plan describing their hazard analysis and preventative controls, which shall be made available to FDA upon request. Failure to comply with this section is a prohibited act under the FDCA. The provision provides flexible compliance timeframes for small and very small businesses, and deems facilities in compliance with existing seafood, juice, and low-acid canned foods regulations to be in compliance with this section.

Sec. 104. Performance Standards – Requires FDA, not less than every 2 years, to determine the most significant food-borne contaminants and, when appropriate to reduce the risk of serious illness or death, prevent adulteration, or prevent the spread of communicable disease, to issue science-based guidance documents, action levels, and/or regulations to prevent adulteration. Performance standards cannot be facility-specific.

Sec. 105. Standards for Produce Safety – Gives FDA the authority to set commodity-specific standards for the safety of fresh produce. States may apply for variances from the standards due to local growing conditions.

Sec. 106. Intentional Adulteration – Requires FDA, working with DHS and USDA, to conduct vulnerability assessments and issue regulations to protect against the intentional adulteration of food.

Sec. 107. Fees – Allows FDA to assess fees for compliance failures (recalls and re-inspections) and participation in a voluntary qualified importer program. Requires appropriated funding to keep pace in order for fees to be collected.

Sec. 108. National Agriculture and Food Defense Strategy – Requires HHS and USDA, in consultation with DHS, to develop a National Agriculture and Food Defense Strategy and research agenda, including specific emergency preparedness, detection, response, and recovery goals.

Sec. 109. Food and Agriculture Coordinating Councils – Requires DHS, in consultation with HHS and USDA, to report to Congress on the activities of the government and private sector coordinating councils for agriculture and food defense, which are designed to improve information sharing between government and private sector partners in protecting the food system.

Sec. 110. Building Domestic Food Safety Capacity – Requires a series of reports and actions intended to focus FDA's attention on several challenges, including information technology, data sharing, research, and government capacity.

Sec. 111. Sanitary Transportation of Food – Requires FDA to promulgate regulations on the sanitary transportation of food.

Sec. 112. Food Allergy and Anaphylaxis Management for Children – Directs HHS, in consultation with the Department of Education, to develop voluntary food allergy management guidelines to manage the risk of food allergy and anaphylaxis in schools or early childhood education programs. Provides for non-renewable food allergy management incentive grants for up to two years to assist local educational agencies (LEAs) with adoption and implementation of the voluntary food allergy management guidelines.

Title II – Improving Capacity to Detect and Respond to Food Safety Problems

Sec. 201. Targeting Inspection Resources – Requires FDA to allocate food inspection resources according to the risk profile of the facility and other important criteria. Requires FDA to increase the frequency of inspections at all facilities, with high-risk facilities inspected annually and other facilities inspected at least once every four years. Requires FDA to submit an annual report to Congress regarding the frequency of, and costs associated with, inspections.

Sec. 202. Laboratory Accreditation – Directs FDA to recognize laboratory accreditation bodies that accredit food testing laboratories and to establish a publicly available registry of these bodies. Requires all laboratory testing done for FDA regulatory purposes to be conducted by either an FDA lab or a lab accredited by an FDA-recognized accreditation body. Requires a report to Congress on the implementation of the national laboratory Food Emergency Response Network, to support early detection, rapid response, and management of food-related emergencies.

Sec. 203. Integrated Consortium of Laboratory Networks – Requires DHS to work with HHS, USDA, and EPA to effectively integrate laboratory networks and other

relevant data sources to optimize national preparedness by quickly sharing information, conducting analyses, and alerting responders.

Sec. 204. Enhancing Traceback and Recordkeeping – Requires FDA, in coordination with the produce industry, to establish pilot projects to test and evaluate new methods for rapidly and effectively tracking and tracing fruits and vegetables. Ensures methods are appropriate for small businesses. Requires FDA, after completion of the pilot project, to establish standards for the types of information, information format, and timeframes for submission of food records to aid the Secretary in rapidly performing trace back activities in the event of a food-borne illness outbreak.

Sec. 205. Pilot Project to Enhance Traceback and recordkeeping with respect to processed food – Requires the Secretary to establish a pilot project to explore and evaluate methods for rapidly and effectively tracing processed food, so that, if an outbreak which involves processed food occurs, the source of the outbreak and recipients of the contaminated food may be quickly identified.

Sec. 206. Surveillance – Requires the Secretary to enhance food-borne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses. Establishes a diverse working group of experts and stakeholders from federal, state, and local food safety and health agencies, the food industry, consumer organizations, and academia to provide recommendations on an ongoing basis regarding the improvement of food-borne illness surveillance. Requires the Secretary to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies.

Sec. 207. Mandatory Recall Authority – Gives FDA the authority to order food recalls when firms fail to voluntarily recall products on their own, when a food is adulterated or contains undeclared allergens and will cause serious adverse health consequences or death to humans or animals. This authority shall only be delegated to the Commissioner of the FDA.

Sec. 208. Administrative Detention – Allows FDA to use administrative detention when FDA has reason to believe that a food is adulterated or misbranded. This is an authority given to FDA in 2002 but never used since, and also the current standard for administrative detention of medical devices.

Sec. 209. Decontamination and Disposal Standards and Plans – Requires EPA, in coordination with HHS, DHS, and USDA, to develop decontamination and disposal standards and protocols to help state and local governments prepare for a food or agriculture emergency.

Sec. 210. Improving the training of State, local, territorial, and tribal food safety officials – Requires the Secretary to set administer training and education programs for

State, local, territorial, and tribal food safety official employees. This training relates to the regulatory responsibilities and other policies established by this legislation.
Sec. 211. Grants to Enhance Food Safety – Authorizes the HHS to make grants to states, localities, and Indian tribes to improve local food safety programs, improve state laboratories and train state officials to conduct food safety inspections.

Title III – Improving the Safety of Imported Food

Sec. 301. Foreign Supplier Verification Program – Requires importers to perform food safety supplier verification activities to mitigate risks in imported foods. Importation of a food by an importer who does not have such a program in place is a prohibited act. Importers required to comply with existing seafood, juice, and low-acid canned foods regulations are deemed to be in compliance with this section.

Sec. 302. Voluntary Qualified Importer Program – Allows importers to qualify for expedited review and importation of food if they go above and beyond the minimum standards to ensure the safety of imported food.

Sec 303. Authority to Require Import Certifications for Food – Allows FDA to require certification or other assurance of safety for high-risk food imports. FDA may refuse admission of a food import lacking required certification.

Sec. 304. Prior Notice of Imported Food Shipments – Requires prior notice for an imported food to include the name of any country that refused entry of the food.

Sec. 305. Review of a Regulatory Authority of a Foreign Country – Gives FDA additional authority to review food safety systems of importing countries to ensure overseas regulators are controlling risks.

Sec. 306. Building Capacity of Foreign Governments with Respect to Food – Requires FDA to develop a comprehensive plan to help expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries.

Sec. 307. Inspection of Foreign Food Facilities – Allows FDA to enter into agreements and arrangements with foreign governments to facilitate the inspection of foreign facilities. Refuses entry of food from a foreign facility or country that fails to permit inspection by the United States.

Sec. 308. Accreditation of Third-Party Auditors and Audit Agents – Directs FDA to recognize accreditation bodies to accredit third parties to certify that foreign food facilities are in compliance with U.S. food safety standards. Third party certification may be used to participate in the Voluntary Qualified Importer Program or to fulfill import certification requirements established by FDA.

Sec. 309. Foreign Offices of the FDA – Directs FDA to establish offices in at least five foreign nations to improve the agency's presence overseas and positively impact the safety of FDA-regulated products.

Sec. 310. Smuggled food – Requires the Secretary of HHS to consult with the Secretary of Homeland Security, Commissioner of Customs and Border Patrol, and the Assistant Secretary for Immigration and Customs Enforcement to develop and implement a strategy to better identify smuggled food and prevent its entry into the United States.

Title IV – Miscellaneous Provisions

Sec. 401. Funding for Food Safety – Increases funding for FDA food safety functions and directs the FDA to incrementally increase field staff by 2014.

Sec. 402. Whistleblower protections – Prohibits retaliation by manufacturers, processors, packagers, transporters, distributers, receivers, holders, or importers against their employees who have, in relation to potential or real food safety violations, provided information to officials, assisted or testified in violation proceedings, or refused to participate in activity that they believe may be a food safety violation.

Sec. 403. Jurisdiction – Clarifies that amendments made by this bill do not change jurisdiction between FDA and USDA, and FDA retains its current food safety authority under the FDCA and the Public Health Service Act.

Sec. 404. Compliance with international agreements – Nothing in the act is to be construed in a manner that is inconsistent with agreements with the World Trade Organization or other international treaties or agreements.